K010557

MAY 2 5 2001

510(k) Summary
JAX™ Granules Bone Void Filler

Submitter's name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's address:	1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number:	901/399-5153
Contact person:	Janet Johnson Green
Date summary prepared:	
Trade or proprietary device name:	JAX Bone Void Filler
Common or usual name:	Bone Void Filler
Classification name:	Unclassified
Device Class:	Class II
Device Product Code and Panel Code:	MQV Panel: Orthopaedics/87

Substantially Equivalent, Legally Marketed Predicate Devices:

MANUFACTURER	DEVICE	510(k) NUMBER	CLEARANCE DATE
Wright Medical Technology	Plaster of Paris Bone Void Filler Kit	K963587	3/24/97
Wright Medical Technology	Osteoset® Pellets	K963562	5/7/97
BioGeneration	ProFusion™ Bone Graft Substitute	K973704	4/3/98
Encore Orthopedics, Inc.	Stimulan™ Calcium Sulfate Bone Void Filler	K982663	2/26/99
Synthes (USA)	Calcium Sulphate Bone Void Filler Pellets	K002362	11/1/00
Howmedic Osteonics	Calcium Sulphate Bone Void Filler Pellets	K001559	6/20/00

Subject device description:
JAX Bone Void Filler, like the predicate devices, is a bone filler manufactured from calcium sulfate powder as its major constituent. Stearic acid and magnesium stearate are mixed with the calcium sulfate powder to form the ***JAX Granules***. The biodegradable, radiopaque granules will be resorbed within 30 to 60 days when used according to labeling instructions. ***JAX Granules*** will be supplied in units of five (5), ten (10), and twenty (20) ccs to accommodate various size voids. Quantities may be modified or expanded as needed.

Subject device intended use:
JAX Granules Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. ***JAX Granules*** is indicated to be gently packed into bony voids or gaps of the skeletal system, (*i.e.*, the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. ***JAX Granules*** provides a filler that resorbs and is replaced with bone during the healing process. Because ***JAX Granules*** is biodegradable and biocompatible, it may be used at an infected site. ***JAX Bone Void Filler*** is provided sterile for single use only.

Technolocgical Characteristics:
JAX Bone Void Filler is similar to legally marketed devices listed above in that all of these devices are indicated for use as a bone void filler, are manufactured from similar or like materials, and are similar in technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2001

Ms. Trude C. McLean
Senior Specialist
Clinical and Regulatory Affairs
Smith and Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K010557
Trade Name: Jax™ Advanced Bone Void Filler
Regulatory Class: unclassified
Product Code: MQV
Dated: February 23, 2001
Received: February 26, 2001

Dear Ms. McLean:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known): K010557

Device Name: ***JAX™ Granules Bone Void Filler***

Indications for Use:

JAX™ Bone Void Filler is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. JAX Granules is indicated to be gently packed into bony voids or gaps of the skeletal system, (*i.e.*, the extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device provides a bone void filler that resorbs and is replaced with bone during the healing process. Because JAX Granules is biodegradable and biocompatible, it may be used at an infected site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Rest[illegible]
and Neurological Devices

510(k) Number K010557

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 601.109)